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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

KEYS, ROSALYND ANN

ART UNIT	PAPER NUMBER
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1621

DATE MAILED: 11/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/026,990

Applicant(s)

HARPER ET AL.

Examiner

Rosalynd Keys

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 and 29-49 is/are pending in the application.
- 4a) Of the above claim(s) 33-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-9,14-21,26,27 and 29-32 is/are rejected.
- 7) ☒ Claim(s) 3,10-13 and 22-25 is/are objected to.
- 8) ☒ Claim(s) 1-27 and 29-49 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 and 4. 6) ☐ Other: _____

DETAILED ACTION

Status of Claims

1. Claims 1-27 and 29-49 are pending.
Claims 1, 2, 4-9, 14-21, 26, 27 and 29-32 are rejected.
Claims 3, 10-13, and 22-25 are objected.
Claims 33-49 are withdrawn from consideration.

Priority

2. Acknowledgment is made of applicant's claim for domestic priority under 35 U.S.C. 119(e).

Election/Restrictions

3. Applicant's election with traverse of Group I, claims 1-32 in Paper No. 6 is acknowledged. The traversal is on the ground(s) that a search of the specifically claimed phenol compounds would necessarily uncover and, therefore, include a search of all potential uses for such compounds, thus, imposing no additional searching burden on the PTO. This is not found persuasive because a search for the claimed phenols would not necessarily uncover and, therefore, include a search of all potential uses for such compounds and in fact the search conducted for the claimed phenol compounds did not uncover its use in a soap, deodorant, ointment or cream as disclosed in claim 37. Also, a search of the claimed phenol compounds uncovered a use, which is other than as an antimicrobial agent (see for example U. S. Patent No. 5,185,377). Further, for a restriction requirement to be proper between a product and

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the process of using the product the Examiner must show that these inventions have acquired a separate status in the art as shown by their different classification. The Examiner has done this. The phenol compounds as claimed are classified in class 568, subclass 638, whereas the method of using the claimed phenols is classified in class 514, subclass 721 (See MPEP 808.02).

The requirement is still deemed proper and is therefore made FINAL.

4. Claims 33-49 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 6.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

6. The information disclosure statements filed September 16, 2002 and June 2, 2003 have been considered.

Claim Objections

7. Claim 1 is objected to because of the following informalities: line 1 of proviso a) 2) contains "ot" after the word 'other'. This appears to be a typo because it does not make sense. Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 4, 6, 16 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claims 4, 16 and 32 recite the compound "2-(2-hydroxyphenoxy)-5-cyclohexylmethylphenol". There is insufficient antecedent basis for this compound in these claims i.e., the compound is not encompassed in the definition given for formulas I, II and III.

11. Claim 6 is vague and indefinite because it is incomplete.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the

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art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 1, 2, 4-9, 14-21, 26, 27 and 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baschong et al. (WO 99/32073) in view of Silverman (The Organic Chemistry of Drug Design and Drug Action, 1992, pages 15-22).

Baschong et al. disclose antimicrobial compounds and oral compositions which are structurally similar to the claimed phenol compounds and compositions (see from last paragraph on page 5 up to the example on page 7).

The phenol compounds of Baschong et al. differ from the instant phenol compounds in the use of chlorine for R₆ instead of methyl as claimed.

Silverman teach that chlorine and methyl are bioisosteres, which have chemical and physical similarities, which produce broadly similar biological properties (see page 19). It is also taught that bioisosterism is a lead modification approach that has been shown to be useful to attenuate toxicity or to modify the activity of a lead (see section D beginning on page 15 and page 19).

One having ordinary skill in the art at the time the invention was made would have found it obvious to substitute the methyl for chlorine in the phenol compounds of Baschong et al. since Silverman teaches that these classical bioisosteres have chemical and physical similarities, which produce broadly similar biological properties. The skilled artisan would have further been motivated to make such a modification in order to manipulate the activity or potency of the phenol compounds.

16. Claims 1, 4, 5, 6, 14, 15, 17, 18, 26, 27 and 28 and are rejected under 35 U.S.C. 103(a) as being unpatentable over Iossifova et al. (Pharmazie, 1994, Vol. 49(4), pages 289-299).

Iossifova et al. disclose compounds which are positional isomers of the claimed phenol compounds (see attached abstract). The compounds of Iossifova et al. are antimicrobial compounds.

Compounds which are position isomers (compounds having the same radicals in physically different positions on the same nucleus) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. *In re Wilder*, 563 F.2d 457, 195USPQ 426 (CCPA 1977).

One having ordinary skill in the art at the time the invention was made would have found the instant phenol compounds obvious over the compounds of lossifova et al. since the compounds have close structural similarity and similar utility.

The instant invention further differs from lossifova et al. in that in the abstract of lossifova et al. there is no disclosure of a composition. Nonetheless, the claimed compositions are obvious over the known compounds because a compound plus carrier is allowable if no utility is disclosed for the old compound. Ex parte Erdmann, 194 USPQ 96. In the instant case the old compound has utility as an antimicrobial agent. The skilled artisan would have been motivated to select carriers which are well known for their suitability for antimicrobial agents.

The instant invention further differs from lossifova et al. in that in the abstract of lossifova et al. fail to disclose the amount of compound present. Nonetheless the claimed amounts are considered obvious because changes in concentration in an old process does not impart patentability unless the recited ranges are critical, i.e., they produce a new and unexpected result. In re Aller et al., (CCPA 1955) 220 F2d 454, 105 USPQ 233.

Allowable Subject Matter

17. Claims 3, 10-13, and 22-25 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosalynd Keys whose telephone number is 703-308-4633. The examiner can normally be reached on M and F 3:00-8:00 pm and T-R 5:30-10:30 am.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 703-308-4532. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

R. Keys

R. Keys
November 26, 2003

Rosalynd Keys

Rosalynd Keys
Primary Examiner
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